

ORIGINAL

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SMITHKLINE BEECHAM CORPORATION dba
GLAXOSMITHKLINE and McKESSON
CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEORGE FISHER,

Plaintiff,

v.

SMITHKLINE BEECHAM
CORPORATION dba
GLAXOSMITHKLINE and McKESSON
CORPORATION,

Defendants.

Case No.

**DECLARATION OF KRISTA L.
COSNER IN SUPPORT OF NOTICE
OF REMOVAL AND REMOVAL,
UNDER 28 U.S.C. § 1441(B)
(DIVERSITY) and 28 U.S.C. § 1441(C)
(FEDERAL QUESTION) OF
DEFENDANT SMITHKLINE
BEECHAM CORPORATION dba
GLAXOSMITHKLINE**

I, KRISTA L. COSNER, declare:

1. I am an attorney admitted to practice before all courts of the State of California and am an Associate with Drinker Biddle & Reath, LLP, attorneys for SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE ("GSK") and McKESSON CORPORATION ("McKesson") (collectively, "Defendants") in this action. I make this Declaration based on my personal knowledge, in support of Defendant GSK's removal of *George Fisher v. SmithKline Beecham Corporation d/b/a GlaxoSmithKline, et al.*, San Francisco Superior Court Case Number CGC-07-468086, to this Court. I would and could competently testify to the matters stated in this Declaration if called as a

1 witness.

2 2. A true and accurate copy of the Complaint in this action is attached as
3 **Exhibit A.**

4 3. A true and accurate copy of the Defendants' Answer to the Complaint
5 ("Answer") in this action is attached as **Exhibit B.** The Complaint and the Answer are
6 the only state court pleadings known to Defendants to have been filed in this action.

7 4. A true and accurate copy of the Judicial Panel on Multidistrict Litigation's
8 Transfer Order, *In re Avandia Marketing, Sales Practices and Products Liability*
9 *Litigation*, MDL 1871 (E.D.P.A.) is attached as **Exhibit C.**

10 5. The original Declaration of Greg Yonko In Support of Defendant's
11 SmithKline Beecham's Notice of Removal and Removal Action Under 28 U.S.C.
12 § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) of Defendant
13 SmithKline Beecham Corporation dba GlaxoSmithKline is attached as **Exhibit D.**

14 6. This is one of many cases that have been filed recently in both federal and
15 state courts across the country involving the prescription drug Avandia.

16 7. Plaintiff's counsel, The Miller Firm, has filed Avandia cases in both state
17 and federal courts, but only in the cases filed in California has The Miller Firm named
18 McKesson or any distributor as a defendant.

19 8. GSK intends to seek the transfer of this action to that Multidistrict
20 Litigation, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*,
21 MDL 1871, and shortly will provide the JPML with notice of this action pursuant to the
22 procedure for "tag along" actions set forth in the rules of the JPML.

23 9. GSK is, and was at the time plaintiff commenced this action, a corporation
24 organized under the laws of the Commonwealth of Pennsylvania with its principal place
25 of business in Philadelphia, Pennsylvania, and therefore is a citizen of Pennsylvania for
26 purposes of determining diversity.

27 10. GSK was served with the Complaint on October 25, 2007.

1 DAVID C. ANDERSEN (State Bar No. 194095)

2 THE MILLER FIRM, LLC

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FILED
San Francisco County Superior Court

OCT 11 2007

GORDON PARK-LI, Clerk

By: Ruth Rutt
Deputy Clerk

SUMMONS ISSUED
CONFERENCE SET

MAR 14 2008 - 9:00 AM

DEPARTMENT 212

8
9 SUPERIOR COURT OF THE STATE OF CALIFORNIA
10 COUNTY OF SAN FRANCISCO

11 Case No. **07-468086**

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14 GEORGE FISHER

15 Plaintiff,

16 v.

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22 SMITHKLINE BEECHAM

23 CORPORATION

24 d/b/a GLAXOSMITHKLINE and

25 MCKESSON CORPORATION

26 Defendants

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- : COMPLAINT FOR DAMAGES
: AND JURY DEMAND
: BASED ON:
: 1. NEGLIGENCE
: 2. NEGLIGENT FAILURE
: TO ADEQUATELY WARN
: 3. NEGLIGENCE *PER SE*
: 4. NEGLIGENT
: MISREPRESENTATION
: 5. BREACH OF EXPRESS
: WARRANTY
: 6. BREACH OF IMPLIED
: WARRANTY
: 7. STRICT PRODUCTS LIABILITY
: DEFECTIVE DESIGN
: 8. STRICT PRODUCTS LIABILITY
: MANUFACTURING AND DESIGN DEFECT
: 9. STRICT PRODUCTS LIABILITY
: FAILURE TO
: ADEQUATELY WARN
: 10. FRAUDULENT
: MISREPRESENTATION
: 11. VIOLATIONS OF CALIFORNIA
: UNFAIR TRADE PRACTICES
: AND CONSUMER PROTECTION LAW
: 12. UNJUST ENRICHMENT
: 13. PUNITIVE DAMAGES

1 **COMPLAINT AND DEMAND FOR JURY TRIAL**

2 Plaintiff, by attorneys, THE MILLER FIRM, LLC, as and for the Verified
3 Complaint herein allege upon information and belief the following:

4 **INTRODUCTION**

5 1. This is an action to recover damages for personal injuries sustained by the Plaintiff,
6 George Fisher, (hereinafter referred to as "Plaintiff"), as the direct and proximate result of the
7 wrongful conduct of the Defendants, SMITHKLINE BEECHAM CORPORATION d/b/a
8 GLAXOSMITHKLINE, (hereinafter referred to as "GSK") and MCKESSON CORPORATION
9 (hereinafter referred to as "McKesson") in connection with the designing, developing,
10 manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-
11 used diabetes prescription drug Avandia (rosiglitazone).

12 2. Defendant GSK designed, researched, manufactured, advertised, promoted,
13 marketed, sold, and/or distributed Avandia.

14 3. Defendant McKesson is a corporation whose principal place of business is San
15 Francisco, California. McKesson distributed and sold Avandia in and throughout the State of
16 California.

17 **JURISDICTION AND VENUE**

18 4. The California Superior Court has jurisdiction over this action pursuant to California
19 Constitution Article VI, Section 10, which grants the Superior Court "original jurisdiction in all
20 causes except those given by statute to other trial courts." The Statutes under which this action is
21 brought do not specify any other basis for jurisdiction.

22 5. The California Superior Court has jurisdiction over the Defendants because, based
23 on information and belief, each is a corporation and/or entity organized under the laws of the State

1 of California, a foreign corporation or association authorized to do business in California and
2 registered with the California Secretary of State or has sufficient minimum contacts in California, or
3 otherwise intentionally avails itself of the California market so as to render the exercise of
4 jurisdiction over it by the California courts consistent with traditional notions of fair play and
5 substantial justice.

6 6. Venue is proper in this Court pursuant to California Code of Civil Procedure Section
7 395 in that Defendant McKesson has its principal place of business in San Francisco.

8 7. Furthermore Defendants GSK and McKesson have purposefully availed themselves
9 of the benefits and the protections of the laws within the State of California. Defendant McKesson
10 has its principal place of business within the state. Defendants GSK and McKesson have had
11 sufficient contact such that the exercise of jurisdiction would be consistent with the traditional
12 notions of fair play and substantial justice.

13 8. Plaintiff seeks relief that is within the jurisdictional limits of the Court.

14 **PARTY PLAINTIFF**

15 9. The Plaintiff, George Fisher, is a natural person and a resident of the State of Texas.

16 **PARTY DEFENDANTS**

17 10. The Defendant, SmithKline Beecham Corporation d/b/a Glaxosmithkline, is a
18 Pennsylvania corporation which has its principal place of business at One Franklin Plaza, 200 N.
19 16th Street, Philadelphia, Pennsylvania 19102.

20 11. At all times material hereto, the Defendant, SmithKline Beecham Corporation d/b/a
21 GlaxoSmithKline was engaged in the business of designing, developing, manufacturing, testing,
22 packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

1 12. Defendant GSK includes any and all parents, subsidiaries, affiliates, divisions,
2 franchises, partners, joint ventures and organizational units of any kind, their predecessors,
3 successors and assigns and their present officers, directors, employees, agents, representatives and
4 other persons action on their behalf.

5 13. Plaintiffs are informed and believe, and based thereon allege, that in committing the
6 acts alleged herein, each and every managing agent, agent, representative and/or employee of the
7 defendant was working within the course and scope of said agency, representation and/or
8 employment with the knowledge, consent, ratification, and authorization of the Defendant and its
9 directors, officers and/or managing agents.

10 14. Upon information and belief, the Defendant, SmithKline Beecham Corporation d/b/a
11 Glaxosmithkline, was formed as a result of the merger of pharmaceutical corporations Glaxo
12 Wellcome, Inc., and SmithKline Beecham, Inc.

13 15. At all times material hereto, the Defendant, McKesson, was a corporation organized,
14 existing and doing business under and by virtue of the laws of the State of Delaware, with its
15 principal place of business in San Francisco, California. McKesson is, and at all times material to
16 this action was, authorized to do business, and was engaged in substantial commerce and business
17 under the laws of the State of California.

18 16. Defendant McKesson includes any and all parents, subsidiaries, affiliates, divisions,
19 franchises, partners, joint ventures and organizational units of any kind, their predecessors,
20 successors and assigns and their present officers, directors, employees, agents, representatives and
21 other persons action on their behalf.

22 17. Plaintiffs are informed and believe, and based thereon allege, that in committing the
23 acts alleged herein, each and every managing agent, agent, representative and/or employee of the

defendant was working within the course and scope of said agency, representation and/or employment with the knowledge, consent, ratification, and authorization of the Defendant and its directors, officers and/or managing agents.

18. At all times relevant to this action, Defendant McKesson packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or to inform users regarding the risks pertaining to, and assuaged concerns about the pharmaceutical Avandia.

BACKGROUND
STATEMENT OF THE CASE

19. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce.

20. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet. Only one other drug like it, pioglitazone, sold as Actos and Actoplus, made by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Avandia faces only one competitor for that market.

21. Avandia had a total U.S. sales of \$2.2 billion in 2006, slightly less than the \$2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between \$90 and \$170. Avandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

22. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

23. GSK's Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death. Not only was GSK aware of the dangers posed by Avandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the New England Journal of Medicine of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular disease.

24. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin. GSK failed to adequately warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was

1 impaired due to GSK's failure to adequately warn of Avandia's defects and GSK's failure to
2 properly and adequately set forth such warnings in Avandia's drug labeling.

3 25. GSK knew of these dangerous defects in Avandia from the many trials which it
4 performed and to which it had access and from its own analysis of these studies, but took no action
5 to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose
6 these dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these
7 dangers through revised drug labeling.

8 26. Not only has GSK failed to disclose in its labeling or advertising that Avandia is
9 actually dangerous for diabetics, GSK has represented and has continued to represent that they
10 manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

11 Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test
12 each investigational drug for the potential to become a new medicine.

13 ***
14

15 Phase I trials typically involve health volunteers. *These trials study the safety of the drug*
16 *and its interaction with the body*, for example, its concentration and duration in the blood following
17 various doses, and begin to answer such questions as whether the drug inhibits or amplifies the
18 effects of other medicines that might be taken at the same time.

19
20 Phase II studies enroll patients with the illness an investigational drug is designed to treat.
21 These trials evaluate whether the drug shows favorable effects in treating an illness and seek to
22 determine the proper dose. They provide an opportunity to explore the therapeutic potential of the
23 drug in what may be quite different illnesses. *The evaluation of safety continues.*

24
25 If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-
26 development program, go forward. *Phase III trials are designed to provide the substantial evidence*
27 *of efficacy and safety required*, in addition to data from earlier-phase trials, before regulatory
28 agencies will approve the investigational drug as a medicine and allow it to be marketed.

29
30 <http://www.gsk.com/research/clinical/index/html> (emphasis supplied).
31

27. GSK has also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer." <http://www.gsk.com/about/index.htm>.

28. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

29. Based on these representations, upon which both Plaintiff and Plaintiff's prescribing physician relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of ingesting Avandia, Plaintiff purchased and ingested Avandia believing that the drug would be safe and effective.

30. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

31. To date, GSK has failed to adequately warn or inform consumers, such as Plaintiff or Plaintiff's prescribing physician, of the known defects in Avandia that can lead to increased risks of cardiovascular events, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

32. As a result of GSK's omissions and/or misrepresentations, Plaintiff ingested Avandia, was diagnosed with congestive heart failure shortly thereafter in 2001, and then suffered a heart attack on or around November 30, 2005, and sustained physical and financial damages including pain and suffering.

COUNT I
NEGLIGENCE
(Against Defendants GSK and McKesson)

33. Plaintiff repeats and reiterates the allegations previously set forth herein.

1 34. That at all times hereinafter mentioned, Defendants were under a duty to exercise
2 reasonable care in the design manufacture, testing processing, marketing advertising, labeling,
3 packaging distribution, and sale of Avandia, and Defendants knew or should have known that
4 Avandia was not safe and that the user could sustain injuries and harm from the drug.

5 35. That Defendants GSK and McKesson negligently, recklessly, grossly negligently,
6 wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others
7 in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the
8 manner that Defendants, directly and indirectly, advertised, marketed and promoted Avandia for the
9 treatment of diabetes, even though Avandia, in fact, was not reasonably safe for such use, and
10 furthermore, Defendants failed to adequately warn of the increased risk of serious cardiovascular
11 events which Defendants knew or should have known about.

12 36. That Defendants GSK and McKesson negligently, recklessly, grossly negligently,
13 wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others
14 by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though
15 such drug was not safe or effective for any purpose because it caused serious cardiovascular events
16 and by failing to adequately warn the trusting public and prescribing health care providers of the
17 true, complete, and accurate risk and the lack of efficacy of Avandia.

18 37. The aforesaid incident and the injuries sustained by Plaintiff were caused by or were
19 contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and
20 conscious and callous disregard of the safety of the public, including Plaintiff, on the part of
21 Defendants in the design, manufacture, distribution, advertising, marketing and promoting of
22 Avandia as being safe and effective in the treatment of diabetes, and by inducing the public,

1 including Plaintiff and Plaintiff's prescribing physician, to believe that Avandia was effective in the
2 treatment of the causes and symptoms of diabetes.

3 38. Defendants GSK and McKesson failed to exercise reasonable care in the design,
4 manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding,
5 distribution and/or sale of Avandia in one or more of the following respects:

- 6 a. Designing, marketing, processing, advertising, packaging, distributing and/or selling a
7 product that defendants knew, or should have known, carried the risk of serious; life-
8 threatening side effects;
9
10 b. Failure to adequately test the product prior to placing the drug Avandia on the market;
11
12 c. Failure to use care in designing, developing and manufacturing their product so as to
13 avoid posing unnecessary health risks to users of such product;
14
15 d. Failure to conduct adequate pre-clinical testing and post-marketing surveillance to
16 determine the safety of Avandia;
17
18 e. Failure to advise consumers, such as plaintiff, that consumption of Avandia could result
19 in severe and disabling side effects, including but not limited to heart injury, excessive
20 fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the
21 heart leading to cardiac arrest and death.
22
23 f. Failure to advise the medical and scientific communities of the potential for severe and
24 disabling side effects, including but not limited to heart injury, excessive fluid retention,
25 fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading
26 to cardiac arrest, and death.
27
28 g. Failure to provide timely and/or adequate warnings about the potential health risks
29 associated with the use of Avandia; and
30
31 h. Any and all other acts of negligence with respect to Avandia which may be shown at
32 trial.

33
34 39. That at all times hereinafter mentioned, upon information and belief, the above-
35 described culpable conduct by Defendants GSK and McKesson was a proximate cause of injuries
36 sustained by Plaintiff.

40. That as a result of the aforesaid occurrence, the injuries sustained by Plaintiff resulting therefrom, Plaintiff suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

41. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

42. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
NEGLIGENT FAILURE TO ADEQUATELY WARN
(Against Defendants GSK and McKesson)

43. Plaintiff repeats and reiterates the allegations previously set forth herein.

44. At all relevant times, defendants GSK and McKesson researched, developed, designed, tested, manufactured, inspected, labeled, and/or distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the pharmaceutical, Avandia, and in the course of same, directly advertised or marketed the product to FDA, consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Avandia.

45. At all relevant times, Avandia was under the exclusive control of the Defendants as aforesaid, and was unaccompanied by appropriate warnings regarding all possible adverse side effects and complications associated with the use of Avandia, dangerous drug-drug interactions and

1 food-drug interactions, and the comparative severity, duration and the extent of the risk of injury
2 with such use.

3 46. At all relevant times, defendants failed to timely and reasonably warn of material
4 facts regarding the safety and efficacy of Avandia so that no reasonable medical care provider
5 would have prescribed, or no consumer would have used, Avandia had those facts been made
6 known to such providers and consumers.

7 47. At all relevant times, defendants failed to perform or otherwise facilitate adequate
8 testing in that such testing would have shown that Avandia posed serious and potentially life-
9 threatening side effects and complications with respect to which full and proper warning accurately
10 and fully reflecting the symptoms, scope and severity should have been made to medical care
11 providers, the FDA and the public, including Plaintiff.

12 48. At all relevant times, Avandia, which was researched, developed, designed, tested,
13 manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into
14 the stream of commerce by Defendants, was defective due to inadequate post-marketing warning
15 and/or instruction because, after Defendants knew or should have known of the risk of serious and
16 potentially life-threatening side effects and complications from the use of Avandia, Defendants
17 failed to provide adequate warnings to medical care providers, the FDA and the consuming public,
18 including Plaintiff, and continued to promote Avandia aggressively.

19 49. As a direct and proximate result of Defendants' carelessness and negligence, the
20 Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain
21 and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
22 significant expenses for medical care and treatment, and will continue to incur such expenses in the
23 future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff

1 has suffered and will continue to suffer economic loss, and has otherwise been physically,
2 emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will
3 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
4 alleged herein.

5 50. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
6 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
7 relief as the Court deems proper.

8 **COUNT III**
9 **NEGLIGENCE PER SE**
10 (Against Defendants GSK and McKesson)

11
12 51. Plaintiff repeats and reiterates the allegations previously set forth herein.

13 52. At all times mentioned herein, Defendants GSK and McKesson had an obligation not
14 to violate the law, in the manufacture, design, formulation, compounding, testing, production,
15 processing, assembling, inspection, research, distribution, marketing, labeling, packaging
16 preparation for use, sale and warning of the risks and dangers of the aforementioned product.

17 53. At all times herein mentioned, Defendants violated the Federal Food, Drug and
18 Cosmetic Act, 21 U.S.C. Section 301 *et seq.*, related amendments and codes and federal regulations
19 provided thereunder, and other applicable laws, statutes and regulations.

20 54. Plaintiff, as a purchaser and consumer of the product, is within the class of persons
21 the statutes and regulations described above are designed to protect, and the injuries alleged herein
22 are the type of harm these statutes are designed to prevent.

23 55. Defendants' acts constitute an adulteration and/or misunderstanding as defined by
24 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and constitutes a breach of duty

1 subjecting Defendants to civil liability for all damages arising therefrom, under theories of
2 negligence *per se*.

3 56. Defendants failed to meet the standard of care set by the applicable statutes and
4 regulations, which were intended for the benefit of individuals such as Plaintiff, making Defendants
5 negligent *per se*: (a) the labeling lacked adequate information on the use of the drug Avandia; (b)
6 the labeling failed to provide adequate warnings of severe and disabling medical conditions as soon
7 as there was reasonable evidence of their association with the drug; (c) there was inadequate
8 information for patients for the safe and effective use of Defendants' drug; (d) there was inadequate
9 information regarding special care to be exercised by the doctor for safe and effective use of
10 Defendants' drug; and (e) the labeling was misleading and promotional.

11 57. As a direct and proximate result of Defendants' carelessness and negligence, the
12 Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain
13 and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
14 significant expenses for medical care and treatment, and will continue to incur such expenses in the
15 future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff
16 has suffered and will continue to suffer economic loss, and has otherwise been physically,
17 emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will
18 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
19 alleged herein.

20 58. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
21 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
22 relief as the Court deems proper.

23 COUNT IV
24 NEGLIGENT MISREPRESENTATION

(Against Defendants GSK and McKesson)

59. Plaintiff repeats and reiterates the allegations previously set forth herein.

60. Defendants GSK and McKesson, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing its statements to be true to Plaintiff, other patients, and the medical community.

61. Defendants GSK and McKesson, through their misrepresentations, intended to induce justifiable reliance by Plaintiff, other patients, and the medical community.

62. Defendants GSK and McKesson, through their marketing campaign and communications with treating physicians, were in a relationship so close to that of Plaintiff and other patients that it approaches and resembles privity.

63. Defendants GSK and McKesson owed a duty to the medical community, Plaintiff, and other consumers, to conduct appropriate and adequate studies and tests for all products, including Avandia, and to provide appropriate and adequate information and warnings.

64. Defendants failed to conduct appropriate or adequate studies for Avandia.

65. Defendants failed to exercise reasonable care by failing to conduct studies and tests of Avandia.

66. As a direct and proximate result of Defendants carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will

1 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
2 alleged herein.

3 67. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
4 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
5 relief as the Court deems proper.

6 **COUNT V**
7 **BREACH OF EXPRESS WARRANTY**
8 **(Against Defendants GSK and McKesson)**
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10 68. Plaintiff repeats and reiterates the allegations previously set forth herein.

11 69. Defendants GSK and McKesson expressly represented to Plaintiff and other
12 consumers and the medical community that Avandia was safe and fit for its intended purposes, that
13 is was of merchantable quality, that it did not produce any dangerous side effects, and that it was
14 adequately tested.

15 70. Avandia does not conform to Defendants' express representations because it is not
16 safe, has numerous and serious side effects, and causes severe and permanent injuries.

17 71. At all relevant times Avandia did not perform as safely as an ordinary consumer
18 would expect, when used as intended or in a reasonably foreseeable manner.

19 72. Plaintiff, other consumers, and the medical community relied upon Defendants'
20 express warranties.

21 73. As a direct and proximate result of the Defendants' breach of express warranty, the
22 Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain
23 and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
24 significant expenses for medical care and treatment, and will continue to incur such expenses in the
25 future. Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has

suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

74. Defendants' conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish them and deter it from similar conduct in the future.

75. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF IMPLIED WARRANTY
(Against Defendants GSK and McKesson)

76. Plaintiff repeats and reiterates the allegations previously set forth herein.

77. The Defendants GSK and McKesson marketed, distributed, supplied and sold the subject product for the treatment of diabetes.

78. At the time that the Defendants GSK and McKesson marketed, distributed, supplied, and sold Avandia, they knew of the use for which the subject product was intended and impliedly warranted it to be of merchantable quality and safe and fit for such use.

79. The Plaintiff, individually and through a prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

80. The Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

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1 87. The subject product is defective and unreasonably dangerous to consumers.

2 88. Avandia is defective in its design or formulation in that it is not reasonably fit,
3 suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated
4 with its design and formulation.

5 89. At all times material to this action, Avandia was expected to reach, and did reach,
6 consumers in this jurisdiction and through the United States, including the Plaintiff herein, without
7 substantial change in the condition in which it was sold.

8 90. At all times material to this action, Avandia was designed, developed, manufactured,
9 tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective
10 and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways
11 which include, but are not limited to, one or more of the following particulars:

12 a. When placed in the stream of commerce, Avandia contained unreasonably dangerous
13 design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks
14 that exceeded the benefits of the subject product, including but not limited to the risks of developing
15 heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe
16 injury to the heart leading to cardiac arrest and death and other serious injuries and side effects in an
17 unacceptably high number of its users;

18 b. When placed in the stream of commerce, Avandia was defective in design and
19 formulation, making the use of Avandia more dangerous than an ordinary consumer would expect,
20 and more dangerous than other risks associated with the other medications and similar drugs on the
21 market for the treatment of diabetes;

22 c. The subject product's design defects existed before it left the control of the Defendants;

23 d. Avandia was insufficiently tested;

1 e. Avandia caused harmful side effects that outweighed any potential utility; and

2 f. Avandia was not accompanied by adequate instructions and/or warnings to fully apprise
3 consumers, including the Plaintiff herein, of the full nature and extent of the risks and side effects
4 associated with its use, thereby rendering Defendants liable to Plaintiff, individually and
5 collectively.

6 91. In addition, at the time the subject product left the control of the Defendants, there
7 were practical and feasible alternative designs that would have prevented and/or significantly
8 reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended
9 function of the product. These safer alternative designs were economically and technologically
10 feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without
11 substantially impairing the product's utility.

12 92. As a direct and proximate result of the subject product's defective design, the
13 Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain
14 and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
15 significant expenses for medical care and treatment, and will continue to incur such expenses in the
16 future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff
17 has suffered and will continue to suffer economic loss, and has otherwise been physically,
18 emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will
19 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
20 alleged herein.

21 93. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
22 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
23 relief as the Court deems proper.

COUNT VIII
STRICT PRODUCTS LIABILITY – MANUFACTURING AND DESIGN DEFECT
(Against Defendants GSK and McKesson)

94. Plaintiff repeats and reiterates the allegations previously set forth herein.

95. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

96. At all times material to this action, Avandia was expected to reach, and did reach, consumers in this jurisdiction and throughout the United States, including the Plaintiff herein without substantial change in the condition in which it was sold.

97. At all times material to this action, Avandia was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Avandia contained manufacturing defects which rendered the product unreasonably dangerous;

b. The subject product's manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. The subject product was not made in accordance with the Defendants' specifications and performance standards;

d. The subject product's manufacturing defects existed before it left the control of the Defendants;

98. As a direct and proximate result of the subject product's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain

1 and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
2 significant expenses for medical care and treatment, and will continue to incur such expenses in the
3 future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff
4 has suffered and will continue to suffer economic loss, and has otherwise been physically,
5 emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will
6 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
7 alleged herein.

8 99. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
9 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
10 relief as the Court deems proper.

11 **COUNT IX**
12 **STRICT PRODUCTS LIABILITY – FAILURE TO ADEQUATELY WARN**
13 **(Against Defendants GSK and McKesson)**

14
15 100. Plaintiff repeats and reiterates the allegations previously set forth herein.

16 101. Avandia was defective and unreasonably dangerous when it left the possession of the
17 Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff
18 herein, of the dangerous risks and reactions associated with the subject product, including but not
19 limited to its propensity to cause heart injury, excessive fluid retention, fluid-overload disease, liver
20 damage, liver failure, and severe injury to the heart leading to cardiac arrest and death and other
21 serious injuries and side effects over other forms of diabetes treatment.

22 102. The Plaintiff was prescribed and used the subject product for its intended purpose.

23 103. The Plaintiff could not have discovered any defect in the subject product through the
24 exercise of reasonable care.

1 104. The Defendants GSK and McKesson, as manufacturers and/or distributors of the
2 subject prescription product, are held to the level of knowledge of an expert in the field.

3 105. The warnings that were given by the Defendants GSK and McKesson were not
4 accurate, clear and/or were ambiguous.

5 106. The warnings that were given by the Defendants GSK and McKesson failed to
6 properly warn physicians of the increased risks of heart injury, excessive fluid retention, fluid-
7 overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest
8 and death and other serious injuries and side effects.

9 107. The warnings that were given by the Defendants GSK and McKesson failed to
10 properly warn consumers of the increased risks of heart injury, excessive fluid retention, fluid-
11 overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest
12 and death and other serious injuries and side effects.

13 108. The Plaintiff, individually and through a prescribing physician, reasonably relied
14 upon the skill, superior knowledge and judgment of the Defendants.

15 109. The Defendants GSK and McKesson had a continuing duty to adequately warn the
16 Plaintiff of the dangers associated with the subject product and of the poor efficacy of the product.

17 110. Had the Plaintiff and/or Plaintiff's prescribing physician received adequate warnings
18 regarding the risks, and the lack of benefits, of the subject product, Plaintiff would not have used it.

19 111. As a proximate result of the subject product's manufacturing defects, the Plaintiff
20 suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and
21 suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred
22 significant expenses for medical care and treatment, and will continue to incur such expenses in the
23 future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff

1 has suffered and will continue to suffer economic loss, and has otherwise been physically,
2 emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will
3 continue into the future. The Plaintiff seeks actual and punitive damages from the Defendants as
4 alleged herein.

5 112. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
6 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
7 relief as the Court deems proper.

8 COUNT X
9 FRAUDULENT MISREPRESENTATION
10 (Against Defendants GSK and McKesson)
11

12 113. Plaintiff repeats and reiterates the allegations previously set forth herein.

13 114. Defendants GSK and McKesson widely advertised and promoted Avandia as a safe
14 and effective medication both in direct-to-consumer marketing and in fraudulent promotion to the
15 health care providers including Plaintiff's prescribing physician.

16 115. Defendants GSK and McKesson had a duty to disclose material information about
17 serious side effects to consumers such as Plaintiff. Additionally by virtue of Defendants' partial
18 disclosures about the medication, in which Defendants touted Avandia as safe and effective
19 treatment, Defendants had a duty to disclose all facts about the risks of use associated with the
20 medication, including the potential for the medication to cause heart injury, excessive fluid
21 retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to
22 cardiac arrest, and death. Defendants intentionally failed to adequately disclose this information for
23 the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

24 116. Had Plaintiff been aware of the hazards associated with Avandia, Plaintiff would not
25 have consumed the product that lead proximately to Plaintiff's adverse health effects.

1 117. Defendants' advertisements regarding Avandia made material misrepresentations to
2 the effect that Avandia was a safe and effective treatment, which misrepresentations Defendant
3 knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase
4 such product. Plaintiff relied in part on these material misrepresentations in deciding to purchase
5 and consume Avandia to his detriment.

6 118. The damages sustained by Plaintiff were a direct and foreseeable result of, and were
7 proximately caused by Defendants' misrepresentations, concealment and omissions.

8 119. Defendants' conduct was willful, wanton, and reckless. Based on the intentionally
9 dishonest nature of Defendants' conduct, which was directed at Plaintiff and the public generally,
10 Defendants should also be held liable for punitive damages.

11 120. Any applicable statutes of limitation have been tolled by Defendants' knowing and
12 active concealment and denial of the facts alleged herein. Plaintiff and other members of the public
13 who were prescribed and who ingested Avandia for the treatment of diabetes have been kept in
14 ignorance of vital information essential to the pursuit of these claims, without any fault or lack of
15 diligence on their part, and could not reasonably have discovered the fraudulent nature of
16 Defendants' conduct, and information and documents concerning the safety and efficacy of
17 Avandia. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in
18 pursuit of this claim.

19 121. By reason of the foregoing, Plaintiff sustained damages in a sum which exceeds the
20 jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition
21 thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be
22 determined upon the trial of this matter.

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1 thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be
2 determined upon the trial of this matter.

3 **COUNT XII**
4 **UNJUST ENRICHMENT**
5 (Against Defendants GSK and McKesson)
6

7 128. Plaintiff repeats and reiterates the allegations previously set forth herein.

8 129. To the detriment of Plaintiffs the Defendants GSK and McKesson have been, and
9 continue to be, unjustly enriched as a result of the unlawful and/or wrongful collection of, inter alia,
10 payments for Avandia.

11 130. Plaintiffs were injured by the cumulative and indivisible nature of the Defendants'
12 conduct. The cumulative effect of the Defendants' conduct directed at physicians and consumers
13 was to artificially create a demand for Avandia at an artificially inflated price. Each aspect of the
14 Defendants' conduct combined to artificially create sales of Avandia.

15 131. The Defendants GSK and McKesson have unjustly benefited through the unlawful
16 and/or wrongful collection of, inter alia, payments for Avandia and continue to so benefit to the
17 detriment and at the expense of Plaintiffs.

18 132. Accordingly, Plaintiffs seek full disgorgement and restitution of the Defendants'
19 enrichment, benefits, and ill-gotten gains acquired as a result of the unlawful and/or wrongful
20 conduct alleged herein.

21 133. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory,
22 treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other
23 relief as the Court deems proper.

24 **COUNT XIII**
25 **PUNITIVE DAMAGES**
26 (Against Defendants GSK and McKesson)

1
2 134. Plaintiff repeats and reiterates the allegations previously set forth herein.

3 135. At all times material hereto, the Defendants GSK and McKesson knew or should
4 have known that the subject product was inherently more dangerous with respect to the risks of
5 heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe
6 injury to the heart leading to cardiac arrest, and death than alternative treatments for diabetes.

7 136. At all times material hereto, the Defendants GSK and McKesson attempted to
8 misrepresent and did misrepresent facts concerning the safety of the subject product.

9 137. Defendants' misrepresentations included knowingly withholding material
10 information from the medical community and the public, including the Plaintiff herein, concerning
11 the safety of the subject product.

12 138. At all times material hereto, the Defendants GSK and McKesson knew and
13 recklessly disregarded the fact that Avandia causes debilitating and potentially lethal side effects
14 with greater frequency than safer alternative methods of treatment for diabetes.

15 139. Notwithstanding the foregoing, the Defendants GSK and McKesson continued to
16 aggressively market the subject product to consumers, including the Plaintiff herein, without
17 disclosing the aforesaid side effects when there were safer alternative methods of treatment for
18 diabetes.

19 140. The Defendants GSK and McKesson knew of the subject product's defective and
20 unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture,
21 market, distribute and sell it so as to maximize sales and profits at the expense of the health and
22 safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the
23 foreseeable harm caused by Avandia.

142. The Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable Plaintiff to weight the true risks of using the subject product against its benefits.

143. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries. The Plaintiff has endured substantial pain and suffering and has undergone extensive medical and surgical procedures. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff's injuries and damages are permanent and will continue into the future.

144. The aforesaid conduct of Defendants GSK and McKesson was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

145. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

1 WHEREFORE, the Plaintiff prays for judgment against Defendants as follows:

- 2 (1) Judgment for plaintiff and against defendants;
- 3 (2) Damages in the form of compensatory damages in excess of the jurisdictional limits,
4 trebled on all applicable counts;
- 5 (3) Physical pain and suffering of the Plaintiff
- 6 (4) Pre and post judgment interest at the lawful rate;
- 7 (5) Reasonably attorneys' fees and costs and expert fees;
- 8 (6) A trial by jury on all issues of the case;
- 9 (7) For any other relief as this court may deem equitable and just;
- 10 (8) Restitution of all purchase costs that Plaintiff paid for Avandia disgorgement of
11 Defendants' profits, and such other relief as provided by law;
- 12 (9) Exemplary and punitive damages in an amount in excess of the jurisdictional limits,
13 trebled on all applicable counts;
- 14 (10) All Bill of Costs elements; and
- 15 (11) Such other relief this Court deems just and proper.

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19 **DEMAND FOR JURY TRIAL**

20 Plaintiff demands a jury trial on all claims so triable in this action.

21 Dated: October 10, 2007

Respectfully submitted,

22
23 *David C. Andersen*
24

25 David C. Andersen (Bar No. 194095)

26 THE MILLER FIRM, LLC

27 Attorneys for Plaintiff

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29 Orange, VA 22960

30 Phone: (540) 672-4224

31 Fax: (540) 672-3055

32 Email: dandersen@doctoratlaw.com

EXHIBIT B

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5 Attorneys for Defendants
6 SMITHKLINE BEECHAM CORPORATION dba
7 GLAXOSMITHKLINE and McKESSON
CORPORATION

8 SUPERIOR COURT OF THE STATE OF CALIFORNIA
9 FOR THE COUNTY OF SAN FRANCISCO

10 GEORGE FISHER,

11 Plaintiff,

12 v.

13 SMITHKLINE BEECHAM
14 CORPORATION dba
15 GLAXOSMITHKLINE and McKESSON
CORPORATION,

16 Defendants.

Case No. CGC-07-468086

**ANSWER TO COMPLAINT BY
DEFENDANTS SMITHKLINE
BEECHAM CORPORATION dba
GLAXOSMITHKLINE AND
McKESSON CORPORATION**

17
18 **INTRODUCTION**

19 Defendants SMITHKLINE BEECHAM CORPORATION dba
20 GLAXOSMITHKLINE ("GSK") and McKESSON CORPORATION ("McKesson")
21 (collectively, the "Defendants"), by and through counsel, hereby respond to the
22 allegations set forth by GEORGE FISHER ("Plaintiff") in his Complaint for Damages
23 (the "Complaint") as follows:

24 **GENERAL DENIAL**

25 By virtue of the provisions of California Code of Civil Procedure §431.30,
26 Defendants generally deny each and every allegation in the unverified Complaint that
27 relates to or is directed to Defendants or any of their alleged agents, servants or
28

ENDORSED
FILED
San Francisco County Superior Court
NOV 19 2007
GORDON PARK-LI, Clerk
BY: BERNADETTE THOMPSON
Deputy Clerk

employees. Defendants further deny that Plaintiff has been damaged to any extent or amount or is entitled to any relief whatsoever from Defendants.

Defendants additionally deny that there is any law, fact, theory or contractual or legal relationship under which Plaintiff is entitled to damages in any amount by these answering Defendants.

Defendants further allege the following affirmative defenses to Plaintiff's Complaint:

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

(Improper Venue)

Venue is improper.

SECOND AFFIRMATIVE DEFENSE

(Insufficiency of Process and Insufficiency of Service of Process)

Process and service of process are insufficient under California law.

THIRD AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

FOURTH AFFIRMATIVE DEFENSE

(Preemption/Primary Jurisdiction)

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Avandia®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the Plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

FIFTH AFFIRMATIVE DEFENSE**(Statute of Limitations/Repose)**

Discovery may show that Plaintiff's claims are barred, in whole or in part, by applicable statutes of limitations, statutes of repose, the doctrine of laches and/or as a result of the failure to allege and/or comply with conditions precedent to applicable periods of limitations and repose.

SIXTH AFFIRMATIVE DEFENSE**(Assumption of Risk)**

Plaintiff knowingly and voluntarily assumed any and all risks as to matters alleged in the Complaint, and such assumption of the risk bars in whole or in part the damages Plaintiff seeks to recover herein.

SEVENTH AFFIRMATIVE DEFENSE**(Contributory/Comparative Negligence)**

At all times mentioned herein, Plaintiff was negligent, careless, and at fault and conducted himself so as to contribute substantially to any alleged risk of injuries and damages. Said negligence, carelessness and fault of Plaintiff bars in whole or in part the damages which Plaintiff seeks to recover herein.

EIGHTH AFFIRMATIVE DEFENSE**(Equitable Defenses)**

Plaintiff's claims are barred by the doctrine of laches, estoppel, waiver, unclean hands and/or failure to preserve evidence.

NINTH AFFIRMATIVE DEFENSE**(Improper Party Defendant)**

McKesson is not a proper party defendant to this action. McKesson was not involved with Avandia[®], a product of GSK.

TENTH AFFIRMATIVE DEFENSE**(Intervening, Superseding Cause)**

The damages allegedly sustained by Plaintiff, if any, were not legally caused by

Defendants, but instead were legally caused by intervening and superseding causes or circumstances.

ELEVENTH AFFIRMATIVE DEFENSE

(Pre-existing Condition or Idiosyncratic Reaction)

The risk of injuries, if any, resulted from a pre-existing and/or related medical condition and/or idiosyncratic reaction and not from any act or omission by or on behalf of Defendants.

TWELFTH AFFIRMATIVE DEFENSE

(Fault of Others)

Plaintiff's alleged injuries, losses, or damages, if any, were caused by the actions negligence, carelessness, fault, strict liability, or omissions of third parties for which Defendants have no control or responsibility.

THIRTEENTH AFFIRMATIVE DEFENSE

(Learned Intermediary)

Plaintiff's claims are barred in whole or in part by the learned-intermediary doctrine.

FOURTEENTH AFFIRMATIVE DEFENSE

(Compliance with FDA Regulations)

At all times relevant, the product was in accordance with and pursuant to all applicable statutes and regulations, including those of the Food and Drug Administration.

FIFTEENTH AFFIRMATIVE DEFENSE

(Immunity for Prescription Drugs and Medical Devices)

The Complaint and each cause of action thereof are barred by the doctrine of immunity for prescription drugs and medical devices, by the Commerce Clause, Article I, Section 8, of the Constitution of the United States as an undue burden upon interstate commerce and/or by the preemption doctrine in that Plaintiff has asserted claims for relief which, if granted, would constitute an impermissible burden by this court on federal laws, regulations and policy relating to the development and marketing of prescription

1 drugs and medical devices in violation of the Supremacy Clause, Article IV, Clause 2 of
2 the Constitution of the United States.

3 **SIXTEENTH AFFIRMATIVE DEFENSE**

4 **(Restatements of Torts)**

5 Defendants affirmatively plead the application of the Restatement (Second) of
6 Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third)
7 of Torts: Products Liability §§ 2, 4 and 6 and comments thereto. Adequate warnings and
8 complete warnings were provided to Plaintiff's prescribing physician, and therefore, the
9 product was not defective or unreasonably dangerous.

10 **SEVENTEENTH AFFIRMATIVE DEFENSE**

11 **(State of the Art)**

12 At all times material hereto, Defendants' conduct and GSK's product, Avandia®,
13 conformed to the state of the art.

14 **EIGHTEENTH AFFIRMATIVE DEFENSE**

15 **(Limitations on Punitive Damages)**

16 With respect to Plaintiff's demand for punitive or exemplary damages, Defendants
17 specifically incorporate by reference all standards of limitations regarding the
18 determination and enforceability of punitive damages awards, including but not limited
19 to, those standards of limitation which arose in *BMW of North America v. Gore*, 517 U.S.
20 559 (1996), *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424
21 (2001), and *State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408 (2003),
22 and *Philip Morris USA v. Williams*, 127 S.Ct. 1057 (2007).

23 **NINETEENTH AFFIRMATIVE DEFENSE**

24 **(Punitive and Exemplary Damages Not Proper)**

25 Plaintiff's claim for punitive damages violates, and it is therefore barred by, the
26 Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the Constitution of the
27 United States of America on grounds including the following:

- 28 a. it is a violation of the Due Process and Equal Protection Clauses of the

1 Fourteenth Amendment to the United States Constitution to impose punitive damages,
2 which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden
3 of proof which is less than the "beyond a reasonable doubt" burden of proof required in
4 criminal cases;

5 b. the procedures pursuant to which punitive damages are awarded may result
6 in the award of joint and several judgments against multiple defendants for different
7 alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection
8 Clauses of the Fourteenth Amendment to the United States Constitution;

9 c. the procedures pursuant to which punitive damages are awarded fail to
10 provide a reasonable limit on the amount of the award against defendant, which thereby
11 violates the Due Process Clause of the Fourteenth Amendment to the United States
12 Constitution;

13 d. the procedures pursuant to which punitive damages are awarded fail to
14 provide specific standards for the amount of the award of punitive damages which
15 thereby violates the Due Process Clause of the Fourteenth Amendment to the United
16 States Constitution;

17 e. the procedures pursuant to which punitive damages are awarded result in
18 the imposition of different penalties for the same or similar acts, and thus violate the
19 Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;

20 f. the procedures pursuant to which punitive damages are awarded permit the
21 imposition of punitive damages in excess of the maximum criminal fine for the same or
22 similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and
23 Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment
24 to the United States Constitution;

25 g. the procedures pursuant to which punitive damages are awarded permit the
26 imposition of excessive fines in violation of the Eighth Amendment to the United States
27 Constitution;

1 h. the award of punitive damages to plaintiffs in this action would constitute a
2 deprivation of property without due process of law; and

3 i. the procedures pursuant to which punitive damages are awarded permit the
4 imposition of an excessive fine and penalty

5 **TWENTIETH AFFIRMATIVE DEFENSE**

6 **(No Failure to Warn)**

7 Defendants at all times discharged any duty to warn through appropriate and
8 adequate warnings in accordance with federal statutes and regulations and with the then-
9 existing states of medical and scientific knowledge.

10 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

11 **(Failure to Plead Fraud with Particularity)**

12 Plaintiff has failed to plead a cause of action for fraud as they have not set forth
13 allegations of fraud with the requisite particularity.

14 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

15 **(Product Safety)**

16 At all times relevant, Avandia® was not unreasonably dangerous or defective.

17 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

18 **(Failure to Join Necessary Party)**

19 Complete relief cannot be accorded among those already parties and, in the
20 alternative, the disposition of this action without the presence of additional, unnamed
21 persons may result in Defendants being subject to a substantial risk of incurring double,
22 multiple, or otherwise inconsistent obligations.

23 **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

24 **(Set Off)**

25 Defendants plead as a set off any monies received by Plaintiff for injuries or
26 damages attributed to the subject incident, including, but not limited to, any insurance
27 proceeds.

28

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Lack of Causation)

Defendants assert that their conduct did not cause, proximately cause, solely cause, or solely proximately cause the injuries and/or damages alleged by Plaintiff.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Good Faith)

Defendants' acts were at all times done in good faith and without malice, with respect to each and every purported cause of action in Plaintiff's Complaint.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Unintentional Acts)

Any alleged act or omission by Defendants concerning the manufacture, distribution, marketing, and/or sale of Avandia® and/or any other conduct in relation thereto was at all times unintentional and resulted from a bona fide error notwithstanding the use of reasonable procedures adopted to avoid any such error, and Defendants made an appropriate correction, repair, replacement, or remedy to the goods once notified of the error.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Conformity with Medical Knowledge)

With respect to each and every purported cause of action in Plaintiff's Complaint, Defendants allege that the methods, standards, and techniques in the preparation of GSK's product, Avandia®, were and are in conformity with the generally recognized state of medical knowledge, common and accepted procedure in the medical field, and state of the art at the time of their preparation.

TWENTY-NINTH AFFIRMATIVE DEFENSE

(Equitable Indemnity)

In the event Defendants are held liable to Plaintiff, which liability is expressly denied, and any other entity is also found liable, Defendants are entitled to a percentage

1 contribution of the total liability from said entity in accordance with principles of
2 equitable indemnity and comparative contribution.

3 **THIRTIETH AFFIRMATIVE DEFENSE**

4 **(Proposition 51)**

5 The liability of Defendants, if any, for Plaintiff's non-economic loss must be
6 apportioned in accordance with the provisions of California Civil Code § 1431.2
7 ("Proposition 51").

8 **THIRTY-FIRST AFFIRMATIVE DEFENSE**

9 **(Failure to Mitigate Damages)**

10 Plaintiff's damages, if any, are barred in whole or in part by Plaintiff's failure to
11 mitigate such damages.

12 **THIRTY-SECOND AFFIRMATIVE DEFENSE**

13 **(No Notice of Breach of Warranty)**

14 Plaintiff failed to give notice of any alleged breach of warranty.

15 **THIRTY-THIRD AFFIRMATIVE DEFENSE**

16 **(Disclaimer of Warranty)**

17 Defendants allege that any and all warranties that may form a basis for Plaintiff's
18 claims for relief were adequately disclaimed as stated by Defendants.

19 **THIRTY-FOURTH AFFIRMATIVE DEFENSE**

20 **(No Reliance on Warranties)**

21 Defendants deny that Plaintiff relied on any warranties alleged in the Complaint.

22 **THIRTY-FIFTH AFFIRMATIVE DEFENSE**

23 **(Unavoidable Circumstances)**

24 The alleged injuries and/or damages of Plaintiff, if any, were the result of
25 unavoidable circumstances that could not have been prevented by anyone.

26 **THIRTY-SIXTH AFFIRMATIVE DEFENSE**

27 **(Misuse)**

28 If Plaintiff sustained injuries or risk of injuries in this action, which allegations are

1 expressly denied, the injuries or risk of injuries were solely caused by and attributable to
2 the unintended, unreasonable, and improper use which Plaintiff made of the product.

3 **THIRTY-SEVENTH AFFIRMATIVE DEFENSE**

4 **(No Strict Liability for Prescription Drugs)**

5 The strict liability causes of action of Plaintiff's Complaint are subject to the
6 limitations placed upon the doctrine of strict product liability for a purported design
7 defect as set forth in *Brown v. Superior Court*, 44 Cal. 3d. 1049 (1988) and its progeny.

8 **THIRTY-EIGHTH AFFIRMATIVE DEFENSE**

9 **(*Buckman v. Plaintiff's Legal Community*)**

10 To the extent Plaintiff's claims are based on alleged misrepresentations or
11 omissions made to the FDA, such claims are barred pursuant to *Buckman v. Plaintiff's*
12 *Legal Community*, 531 U.S. 341 (2001).

13 **THIRTY-NINTH AFFIRMATIVE DEFENSE**

14 **(Standing)**

15 Plaintiff lacks standing to bring some or all of the claims alleged in the Complaint.

16 **FORTIETH AFFIRMATIVE DEFENSE**

17 **(Unconstitutional Claims)**

18 Defendants allege that granting Plaintiff's requested relief under California
19 Business and Professions Code § 17200 et seq. ("BPC 17200"), and/or the Consumers
20 Legal Remedies Act, California Civil Code § 1750 et seq. ("CLRA"), would violate
21 Defendants' rights under the United States and California constitutions.

22 **FORTY-FIRST AFFIRMATIVE DEFENSE**

23 **(Adequate Remedy at Law)**

24 Plaintiff's causes of action under BPC 17200 and/or the CLRA, and the remedies
25 sought thereunder, are barred because there is an adequate remedy at law.

26 **FORTY-SECOND AFFIRMATIVE DEFENSE**

27 **(Unjust Enrichment)**

28 Any and all BPC 17200 claims are barred, in whole or in part, on the basis that

1 Plaintiff would be unjustly enriched if allowed to recover damages thereunder.

2 **FORTY-THIRD AFFIRMATIVE DEFENSE**

3 **(Remedies for Third Parties Barred)**

4 Plaintiff's causes of action under BPC 17200 and the remedies sought thereunder,
5 are barred because Plaintiff seeks remedies for parties that have not been injured and
6 there are no identifiable injured parties.

7 **FORTY-FOURTH AFFIRMATIVE DEFENSE**

8 **(Plaintiff not Competent Party)**

9 Plaintiff's causes of action under BPC 17200 and the remedies sought thereunder,
10 are barred because the Complaint has not been filed by competent plaintiffs for the
11 benefit of injured parties.

12 **FORTY-FIFTH AFFIRMATIVE DEFENSE**

13 **(Administrative or Regulatory Schemes Bar Recovery/Abstention)**

14 Plaintiff's causes of action under BPC 17200 and the remedies sought thereunder,
15 are barred by the existence of a comprehensive administrative or regulatory scheme
16 which would redress the actions complained of by Plaintiff. This Court should dismiss or
17 stay Plaintiff's BPC 17200 claim in deference to this administrative or regulatory
18 scheme.

19 **FORTY-SIXTH AFFIRMATIVE DEFENSE**

20 **(Failure to Give Preliminary Notice)**

21 Plaintiff has failed to comply with the CLRA notice requirements of California
22 Civil Code § 1782.

23 **FORTY-SEVENTH AFFIRMATIVE DEFENSE**

24 **(Choice of Law)**

25 Defendants are entitled to the benefit of all defenses and presumptions contained
26 in, or arising from, any rule of law or statute of any other state whose substantive law
27 might control the action.

28

FORTY-EIGHTH AFFIRMATIVE DEFENSE

(Other Defenses)

Defendants hereby give notice that they intend to rely upon any other affirmative defenses pled by any other defendant and not pled by themselves in this action to the extent they do not conflict with Defendants' own affirmative defenses. Defendants reserve their right to amend their Answer to assert any additional defenses and matters in avoidance that may be disclosed during the course of additional investigation and discovery.

JURY DEMAND

Defendants request a trial by jury of this matter.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray:

1. That the Complaint be dismissed with prejudice as to the answering Defendants and that judgment be entered in their favor;
2. For costs of suit incurred herein;
3. And for such other relief as the Court may deem just and appropriate.

Dated: November 19, 2007

DRINKER BIDDLE & REATH LLP


DONALD F. ZIMMER, JR.
KRISTA L. COSNER

Attorneys for Defendants
SMITHKLINE BEECHAM
CORPORATION dba
GLAXOSMITHKLINE and McKESSON
CORPORATION

CERTIFICATE OF SERVICE

I, LEE ANN L. ALLDRIDGE, declare that:

I am at least 18 years of age, and not a party to the above-entitled action. My business address is 50 Fremont Street, 20th Floor, San Francisco, California 94105, Telephone: (415) 591-7500.

On November 19, 2007, I caused to be served the following document(s):

ANSWER TO COMPLAINT BY DEFENDANTS SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE AND McKESSON CORPORATION

by enclosing a true copy of (each of) said document(s) in (an) envelope(s), addressed as follows:

- ☒ BY MAIL: I am readily familiar with the business' practice for collection and processing of correspondence for mailing with the United States Postal Service. I know that the correspondence is deposited with the United States Postal Service on the same day this declaration was executed in the ordinary course of business. I know that the envelope was sealed, and with postage thereon fully prepaid, placed for collection and mailing on this date, following ordinary business practices, in the United States mail at San Francisco, California.
- ☐ BY PERSONAL SERVICE: I caused such envelopes to be delivered by a messenger service by hand to the address(es) listed below:
- ☐ BY OVERNIGHT DELIVERY: I enclosed a true copy of said document(s) in a Federal Express envelope, addressed as follows:
- ☐ BY FACSIMILE: I caused such documents to be transmitted by facsimile transmission and mail as indicated above.

David C. Anderson
THE MILLER FIRM, LLC
108 Railroad Avenue
Orange, VA 22960
Telephone: (540) 672-4224
Facsimile: (540) 672-3055

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on November 19, 2007 at San Francisco, California.

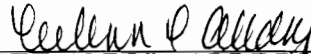

LEE ANN L. ALLDRIDGE

EXHIBIT C

MDL 1871

UNITED STATES
JUDICIAL PANEL ON
MULTIDISTRICT LITIGATION

7:23 am, Oct 16, 2007

FILED
CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: AVANDIA MARKETING, SALES PRACTICES
AND PRODUCTS LIABILITY LITIGATION

Sharon Ann Dabon v. GlaxoSmithKline, Inc.,)
E.D. Louisiana, C.A. No. 2:07-3041)
Celenio Cruz-Santana v. GlaxoSmithKline, PLC, et al.,)
D. Puerto Rico, C.A. No. 3:07-1461)

MDL No. 1871

TRANSFER ORDER

Before the entire Panel: Plaintiff in the action pending in the Eastern District of Louisiana, has moved, pursuant to 28 U.S.C. § 1407, to centralize this litigation in the District of Puerto Rico or, alternatively, in the Eastern District of Louisiana. This litigation currently consists of moving plaintiff's action and one action pending in the District of Puerto Rico.¹ Plaintiff in the latter action supports centralization in the District of Puerto Rico. Plaintiffs in potential tag-along actions pending in the Central District of California, the Southern District of Florida, the District of New Jersey, the Southern District of New York, and the District of Puerto Rico have submitted responses in support of centralization. These plaintiffs suggest a variety of fora for transferee district, including the Southern District of Florida (favored by plaintiffs in the action pending in that district), the District of New Jersey (favored by plaintiff in the action pending in that district, as well as plaintiff in the Central District of California action), the Southern District of New York (favored by plaintiffs in eight actions pending in that district), and the District of Puerto Rico (favored by plaintiffs in the action pending in that district). Responding defendant SmithKlineBeecham Corp. d/b/a GlaxoSmithKline (GSK) initially opposed the Section 1407 motion, but now supports centralization in the Eastern District of Pennsylvania.

* Judge Heyburn took no part in the disposition of this matter.

¹ The Panel has been notified of 28 additional related actions pending in the Western District of Arkansas, the Central District of California (two actions), the Southern District of Florida (two actions), the Southern District of Illinois, the Southern District of Indiana, the Eastern District of Louisiana, the District of New Jersey, the Eastern District of New York, the Southern District of New York (ten actions), the Northern District of Ohio, the Eastern District of Oklahoma, the Eastern District of Pennsylvania, the District of Puerto Rico, the Eastern District of Tennessee, the Western District of Tennessee, and the Eastern District of Texas (two actions). These actions and any other related actions will be treated as potential tag-along actions. See Rules 7.4 and 7.5, R.P.J.P.M.L., 199 F.R.D. 425, 435-36 (2001).

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PLEADING NO. 22

- 2 -

On the basis of the papers filed and hearing session held, we find that these actions involve common questions of fact, and that centralization under Section 1407 in the Eastern District of Pennsylvania will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Both actions arise from allegations that certain diabetes drugs manufactured by GSK – Avandia and/or two sister drugs containing Avandia (Avandamet and Avandaryl) – cause an increased risk of heart attack and other physical injury, and that GSK failed to provide adequate warnings concerning that risk. Centralization under Section 1407 will eliminate duplicative discovery, avoid inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary.

We are also persuaded that the Eastern District of Pennsylvania is an appropriate transferee district for pretrial proceedings in this litigation. GSK's principal place of business is located in that district, and thus many witnesses and documents relevant to the litigation are likely to be found there. In addition, one of the potential tag-along actions was commenced in the Eastern District of Pennsylvania.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the two actions are transferred to the Eastern District of Pennsylvania and, with the consent of that court, assigned to the Honorable Cynthia M. Rufe for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION



D. Lowell Jensen
Acting Chairman

John G. Heyburn II, Chairman*
Robert L. Miller, Jr.
David R. Hansen

J. Frederick Motz
Kathryn H. Vratil
Anthony J. Scirica

DONALD F. ZIMMER, JR. (State Bar No. 112279)
KRISTA L. COSNER (State Bar No. 213338)
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Attorneys for Defendants
SMITHKLINE BEECHAM CORPORATION dba
GLAXOSMITHKLINE and McKESSON
CORPORATION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

GEORGE FISHER,

Plaintiff,

v.

SMITHKLINE BEECHAM
CORPORATION dba
GLAXOSMITHKLINE and McKESSON
CORPORATION,

Defendants.

Case No.

**DECLARATION OF GREG YONKO IN
SUPPORT OF NOTICE OF REMOVAL
AND REMOVAL ACTION, UNDER 28
U.S.C. § 1441(B) (DIVERSITY) and 28
U.S.C. § 1441(C) (FEDERAL
QUESTION) OF DEFENDANT
SMITHKLINE BEECHAM
CORPORATION dba
GLAXOSMITHKLINE**

I, GREG YONKO, declare:

1. I am Senior Vice President - Purchasing for McKesson Corporation ("McKesson"), and make this declaration in support of the Notice of Removal and Removal Action of defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK") based on my personal knowledge.

2. I have been in my current position since 1997, and have been employed by McKesson for over 25 years. As Vice President of Purchasing, I am responsible for purchasing prescription and non-prescription branded product management and investment purchasing.

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GREG YONKO